9. (Amended) The pharmaceutical composition of claim 1, wherein the plant essential oil compound is carvacrol.

10. (Amended) The pharmaceutical composition of claim 1, wherein the plant essential oil compound is cinnamic alcohol.

11. (Amended) The pharmaceutical composition of claim 1, wherein the plant essential oil compound is cinnamic aldehyde.

12. (Amended) The pharmaceutical composition of claim 1, wherein the plant essential oil compound is citronellal.

13. (Amended) The pharmaceutical composition of claim 1, wherein the plant essential oil compound is trans-anethole.

REMARKS

Claims 1-13 are pending in the application. Claims 6-13 have been previously withdrawn from consideration as being directed to non-elected subject matter. Claim 14 is cancelled without prejudice to, or disclaimer thereof, the subject matter it contains. Claims 1, 4 and 5 are amended in an effort to encompass infringing subject matter. No new matter is added into the application.

The Office Action maintains the restriction and election of species requirements and makes them final. The Office Action further states, as follows.

> Claims 1-5 read on the elected invention. Claims 6-14 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species, the requirement having been traversed in Paper No. 6 filed January 08, 2001.

Applicants respectfully maintain its traversal for the reasons of record. Further and in regards to the election requirement, Applicants understand that (a) the restriction requirement to Claims 6-

13 will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims. It is believed that at least Claim 1 is generic to a plurality of species, including without limitation Claims 5 through 13 which are part of elected Group I.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned, "Version With Markings To Show Changes Made."

Applicants respectfully submit that entry of the above claim amendments is proper under 37 C.F.R. § 1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issues requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout the prosecution); (c) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (d) place the application in better form for appeal. Thus, entry of the foregoing amendments, reconsideration and reexamination of the claimed subject matter are respectfully requested.

The Rejections Under 35 U.S.C. §102(b)

Claims 1-5 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ref U (Kim et al., *Antianaphylactic Properties of Eugenol*, 36(6) Pharmacological Research, 475-480 (1997)), Ref V (Oita et al., 1985:427328, Ref W (Caplus 1991:115063), or REF X (Luc et al., WO 93/09770). The Office Action states:

> Each of the references teaches a pharmaceutical composition that is considered to be within the scope of the broad claimed language as stated in the previous Office action in view of the following decision:
>
> It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce[d] by identical or substantially identical process, the PTO can require an applicant to prove that the prior art

products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see **In re Brown**, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); **In re Best**, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977).

The rejection of the claims will be maintained absent a showing that the compositions of the references are not within the scope of the claimed products. It is acknowledged that the references do not have the claimed use but a new use for an old composition is not patentable in this particular application.

The cited references Kim et al. (Ref. U), Oita et al. (Ref V), DE 3829200 (Ref. W) and Luc et al. (Ref. X) do not anticipate or disclose Applicants' invention as recited in the amended claims. At best, Kim et al. discloses a eugenol and saline composition having an effect on anaphylaxis. Oita et al. merely discloses an opthalmic pharmaceutical comprising eugenol. At best, DE 3829200 discloses a compound for the treatment of AIDS containing "e[u]genol and isoe[u]genol" or clove oil. Finally, Luc et al. merely discloses a synergistic bacteriacidal composition comprising chlorhexidine and eugenol for the treatment of buccal cavity and dermatological infections. The cited references do not expressly and specifically disclose all the features of the claimed invention. None of the references reveal, let alone suggest or teach, the antiestrogenic activity against E_2-induced abnormal cell growth, as required by the claims. To the extent the Office Action relies on the doctrine of inherency, inherency does not mean that the compositions of the four cited references might have antiestrogenic activity, but it must be disclosed, if inherency is claimed, that the composition will necessarily have antiestrogenic activity. Standard Oil Co. v. Montedison, S.p.A., 494 F.Supp. 370, Application of Draeger, 150 F.2d 572, 574 (32 CCPA 1217) (C.C.P.A. 1954). Thereby, References U, V, W and X are deficient in at least one essential element of Applicants' composition and therefore do not anticipate the claimed invention. Thus, the rejections under §102(b) based on References U, V,

W and X should be reconsidered and withdrawn, and such favorable action is respectfully requested.

If any issues remain outstanding or if an Examiner's amendment could be made to expedite prosecution, then Applicants respectfully invite the Examiner to contact the undersigned representative at the telephone number listed below.

Please grant any extensions of time deemed necessary for entry of this communication. Please charge any deficient fees, including Notice of Appeal fees, or credit any overpayment of fees, to Deposit Account No. 5000417.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this document (including any paper referred to as being attached or enclosed) is being sent to the U.S. Patent and Trademark Office via facsimile transmission to (703) 305-7939 on the date indicated below, with a coversheet addressed to Assistant Commissioner for Patents, U.S. Patent and Trademark Office, Washington, D.C., 20231.

Date: 10/01/2001

By: Kelli N. Watson
Kelli N. Watson, Registration No. 47,170

ATTACHMENT
Version With Markings To Show Changes Made

IN THE CLAIMS

1. (Amended) A pharmaceutical composition for the prevention or treatment of soft tissue cancer in mammals, comprising, in admixture with a pharmaceutically acceptable carrier, at least one plant essential oil compound selected from the group consisting of aldehyde C16 (pure), amyl cinnamic aldehyde, amyl salicylate, anisic aldehyde, benzyl alcohol, benzyl acetate, cinnamaldehyde, cinnamic alcohol, α-terpineol, carvacrol, carveol, citral, citronellal, citronellol, p-cymene, diethyl phthalate, dimethyl salicylate, dipropylene glycol, eucalyptol (cineole), eugenol, iso-eugenol, galaxolide, geraniol, guaiacol, ionone, d-limonene, menthol, methyl anthranilate, methyl ionone, methyl salicylate, α-phellandrene, pennyroyal oil, perillaldehyde, 1- or 2-phenyl ethyl alcohol, 1- or 2-phenyl ethyl propionate, piperonal, piperonyl acetate, piperonyl alcohol, D-pulegone, terpinen-4-ol, terpinyl acetate, 4-tert butylcyclohexyl acetate, thyme oil, thymol, metabolites of trans-anethole, vanillin, and ethyl vanillin, wherein the plant essential oil has antiestrogenic activity against E_2-induced abnormal cell growth.

4. (Amended) The pharmaceutical composition of claim 1, wherein the [soft tissue cancer]E_2-induced abnormal cell growth is breast cancer.

5. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is eugenol.

6. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is thymol.

7. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is isoeugenol.

8. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is benzyl alcohol.

9. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is carvacrol.

10. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is cinnamic alcohol.

11. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is cinnamic aldehyde.

12. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is citronellal.

13. (Amended) The pharmaceutical composition of claim 1[2], wherein the plant essential oil compound is trans-anethole.